IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

PATTI POKORNY AND CHRISTOPHER POKORNY (H/W), Plaintiffs, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 4:14-cv-02960

DEFENDANT'S MEMORANDUM OF LAW
IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL
THE PRODUCTION OF SALES REPRESENTATIVES' CUSTODIAL FILES

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Plaintiffs' motion acknowledges that their claims arise from the theory that Lilly did not adequately warn of the risk of discontinuation symptoms when stopping Cymbalta treatment. Yet Plaintiffs move to compel discovery related to Lilly's communications with two of Ms. Pokorny's doctors who played no role in the decision to prescribe Cymbalta to her and did not oversee her discontinuation from Cymbalta. Plaintiffs fail to establish any connection between the additional sales representative discovery they seek through this motion and the claims in this case. Indeed, Plaintiffs' apparent willingness to abandon these requests entirely in favor of an admission of causation by Lilly (Pl. Mem. at 5-6) constitutes an acknowledgment that none of the discovery at issue here is critical to their claims. The Federal Rules do not permit a party to use the *in terrorem* effect of threatened discovery as a tool to extract unrelated case concessions. Rather, the Rules envision that discovery will provide a vehicle for gathering facts relevant to the claims at issue and proportional to what is at stake in the litigation.

In that vein, Lilly has already produced substantial discovery on the question of what information it shared with doctors generally and Plaintiff's prescribing physicians specifically, including a wide range of documents relating to Lilly's promotion and marketing of Cymbalta and materials provided to doctors. In addition, Lilly has produced information on sales representative training, data on sales calls by Lilly representatives to Ms. Pokorny's doctors, and the email files of three sales representatives who actually visited Ms. Pokorny's Cymbalta prescriber and the doctor who tapered her off the medicine. And Lilly has presented those three sales representatives for deposition already.

The additional sales representative discovery Plaintiffs seek also fails the principle of proportionality that defines the scope of permissible discovery under the Rules. Indeed, it is altogether likely that the cost to Lilly of carrying out just the additional discovery sought by this

motion would outstrip the amount at stake here, where the claim at its best involves a transient and short term discomfort with no ongoing impact. Given the peripheral and marginal relevance of the requested documents, the corresponding burden of collecting, reviewing, and producing these materials, and the modest nature of Ms. Pokorny's alleged injuries, the Court should find such discovery unwarranted and deny Plaintiffs' motion to compel.

BACKGROUND

I. Plaintiffs' Claims

Cymbalta is an FDA-approved prescription medication used to treat various pain and psychiatric disorders. It is in a class of medicines known as serotonin-norepinephrine reuptake inhibitors (SNRIs). Plaintiffs' case is one of many pending across the country, each of which claims that Lilly failed to warn adequately of the risk of potential symptoms upon discontinuation of Cymbalta. Of the cases litigated to a merits determination, Lilly has won summary judgment in two suits (including on the adequacy of the Cymbalta discontinuation warning) and prevailed in three trials involving four plaintiffs, including securing a jury finding that the Cymbalta warning was adequate. *See Hagan-Brown v. Eli Lilly & Co.*, 1:14-cv-01614-AJT-JFA (E.D. Va. Sept. 1, 2015) (jury verdict for Lilly on warning adequacy); *Ali v. Eli Lilly & Co.*, 1:14-cv-01615 (AJT/JFA) (E.D. Va. Sept. 1, 2015) (same); *Herrera v. Eli Lilly & Co.*, No. 2:13-cv-02702 (C.D. Cal. Aug. 10, 2015) (defense verdict for Lilly on all claims); *Hexum v. Eli Lilly & Co.*, No. 2:13-cv-02701-SVW-MAN (C.D. Cal. Aug. 18, 2015) (directed verdict for Lilly entered at close of plaintiff's case); *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391 (S.D.N.Y. 2014) (granting judgment for Lilly on adequacy of warning), *reconsideration denied*, 2015 WL 845720 (S.D.N.Y. Feb. 26, 2015); *Carnes v. Eli Lilly & Co.*, No. 0:13-591-CMC, 2013 WL 6622915 (D.S.C. Dec. 16, 2013) (granting summary judgment to defendant).

An inherent risk of stopping any antidepressant therapy is the potential for a patient to experience certain unwanted effects, which the medical community describes as "discontinuation" symptoms. The medical community understands the potential for these symptoms, practice guidelines discuss this risk, and all antidepressant labeling includes information about this phenomenon. Since Cymbalta was first approved by the U.S. Food and Drug Administration ("FDA") in 2004, its label has included a detailed, three-paragraph warning about the risk of discontinuation symptoms. The label in place at the time of Plaintiff's prescription was approved by the FDA in 2005 and stated:

> Discontinuation of Treatment with Cymbalta
>
> Discontinuation symptoms have been systematically evaluated in patients taking Cymbalta. Following abrupt discontinuation in MDD placebo-controlled clinical trials of up to 9-weeks duration, the following symptoms occurred at a rate greater than or equal to 2% and at a significantly higher rate in Cymbalta-treated patients compared to those discontinuing from placebo: dizziness; nausea; headache; paresthesia; vomiting; irritability; and nightmare.
>
> During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.
>
> Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate (*see* DOSAGE AND ADMINISTRATION).

Cymbalta Package Insert at 9-10 (October 2005), Ex. 1.

Plaintiff Patti Pokorny was prescribed Cymbalta in 2005 by her neurologist Dr. Luciana De Saibro for the treatment of idiopathic peripheral neuropathy, which manifested as burning and tingling in her feet. Deposition of Patti Pokorny ("Pokorny Dep.") at 92:2-93:16, 105:16-106:3 (Sept. 12, 2015), Ex. 2; Compl. ¶ 31 (October 17, 2014), Ex. 3. During Ms. Pokorny's seven-year Cymbalta treatment, she saw two additional neurologists who continued to prescribe Cymbalta to her. For an interim period, Ms. Pokorny's neurologist requested that her primary care physician, Dr. Kathryn Ziegler, refill her Cymbalta prescription. Pokorny Dep. at 156:17-157:20, Ex. 2. Ms. Pokorny decided to discontinue the medication in September 2012 and was given instructions for tapering off Cymbalta by her neurologist at that time, Dr. Fatima Ibrahim. *Id.* at 179:18-20, 185:21-186:13, Ex. 2. Ms. Pokorny ultimately stopped the medicine entirely in early November of that year. *Id.* She alleges that she experienced discontinuation symptoms of "brain zaps, suicidal ideations, nausea, hallucination, vomiting, insomnia, elevated blood pressure, stomach bloating, and excessive night sweats," although she initially reported only shakiness and nausea to her doctor. Compl. ¶ 33, Ex. 3; Pokorny Dep. at 192:15-193:11, Ex. 2. Ms. Pokorny reported most of her symptoms after she had already contacted an attorney about bringing this lawsuit against Lilly. Pokorny Dep. at 196:10-198:18, Ex. 2. Ms. Pokorny's injuries were transient and limited—Mr. Pokorny testified his wife's alleged Cymbalta discontinuation symptoms were confined to the last two to three months of 2012, and certain symptoms lasted only two or three weeks. Deposition of Christopher Pokorny at 61:5-17, 77:17-21, Ex. 4. By January 16, 2013, Ms. Pokorny reported to her doctor that she "fel[t] like herself again." Pokorny Dep. at 216:10-18, Ex. 2. She alleges no continuing physical symptoms. *Id.* at 224:22-25.

II. The Discovery Record

A. Lilly's Extensive Production of Marketing and Promotional Materials

Lilly has already produced more than 35,000 pages of documents relating to Lilly's communication with Ms. Pokorny's doctors about Cymbalta and has agreed to produce more upon a reasonably diligent search, including:

- All advertisements and promotional materials directed at either health care professionals or consumers, as submitted to the FDA's Office of Prescription Drug Promotion, consisting of more than 15,000 documents;
- Lilly's Dear Healthcare Professional letters concerning Cymbalta;
- Documents reflecting inquiries from health care professionals and consumers to Lilly about Cymbalta discontinuation;
- Medical information letters sent to health care professionals concerning Cymbalta and discontinuation-emergent adverse events;
- Cymbalta brand plans;
- Market surveys and related materials concerning Cymbalta and discontinuation-emergent adverse events;
- Most recent training materials for sales representatives;
- Exemplars of packaging and accompanying materials for samples of Cymbalta;
- Health-care-provider-level prescription data for Plaintiff's doctors as identified by Plaintiff;
- Records from Lilly's incentive compensation system reflecting performance-based metrics for the sales representatives that called on Plaintiff's doctors;
- Spreadsheets tracking sales calls to Plaintiff's doctors;

- Records of any compensation paid to Plaintiff's doctors;
- Written agreements, contracts, liability releases, or legal documents between Lilly and Plaintiff's doctors; and
- Records of attendance by Plaintiff's doctors at Cymbalta-related programs sponsored by Lilly.

Declaration of Emily Ullman ¶ 3.

Many of these categories address the types of documents contained in sales representative files, particularly training materials, records from Lilly's incentive compensation system, sales call trackers, and advertising and promotional materials. These documents are only a subset of the extensive discovery record in this litigation, to which Plaintiffs have access. Over the past three years of litigation, Lilly has produced more than three million pages of documents, and there have been eleven depositions of current and former Lilly employees, including 30(b)(6) depositions on a range of topics.[1] This discovery touches on all aspects of the life cycle of Cymbalta, including development, approval, marketing, and post-marketing surveillance.

B. The Discovery Dispute at Issue

Plaintiffs' motion comes after a long negotiation between the parties on sales representative discovery. In their First Requests for Production, Plaintiffs requested production of the complete "custodial file"—a term Plaintiffs do not define—of every Lilly sales representative who called on Ms. Pokorny's doctors regarding Cymbalta and every document that those sales representatives showed to or left with those doctors. Def. Objs. & Resp. to Pls. First Set of Request for Production No. 91 at 63-64, Ex. 5. Lilly objected to this request as

[1] Two additional Lilly employees are scheduled to be deposed this month.

overbroad, unduly burdensome, and not limited to Cymbalta and discontinuation-emergent adverse events. *See id.* at 64-65.

To help Plaintiffs narrow their request, Lilly produced a spreadsheet identifying the various Lilly sales representatives who made Cymbalta-related calls on four of Ms. Pokorny's doctors from the launch of the medication through the present. Plaintiffs selected 13 sales representatives and requested production of their full "custodial files," including emails, hard copy documents, and system files. Although Lilly offered to work with Plaintiffs to develop a set of search terms to ensure production was focused on documents related to Cymbalta discontinuation, Plaintiffs refused to agree to any limitations on the production other than dates. Having reached an impasse, Plaintiffs then moved to compel these files in October 2015. *See* Pls. Oct. 1, 2015 Mot. to Compel (Dkt. 23).

While the motion was pending, the parties continued to negotiate and came to an agreement on a search term protocol that would be run against certain sales representatives' emails. Lilly agreed to produce responsive emails and attachments for three sales representatives (Jason Bott, Kevin Gray, and Susanne Salas) who called on Ms. Pokorny's initial prescribing physician and the neurologist who oversaw her discontinuation of Cymbalta. *See* Joint Mot. to Amend Scheduling Order at 2 (Dkt. 30). In light of this agreement, the Court denied Plaintiffs' motion as moot. Lilly subsequently agreed to produce the responsive emails of one additional sales representative, Brook Finlinson, who also called on Ms. Pokorny's initial Cymbalta prescriber, and offered to produce the responsive emails from another sales representative, which Plaintiffs declined. *See* Email from Emily Ullman to Meredith Gray (Dec. 30, 2015), Ex. 6. Pursuant to the agreed-upon search protocol, Lilly has produced 517 documents from the three sales representatives who have been deposed to date and will produce approximately 100 more

from Mr. Finlinson. Furthermore, Mr. Bott, Mr. Gray, and Ms. Salas have all been deposed by Plaintiffs.

Of the remaining sales representatives, Plaintiffs insist on production of materials from four additional sales representatives: Brooke Adams, Marcus Julien, Traci Korkowsi, and Rosalind Sobosle.[2] These sales representatives did not call on the physician who initially prescribed Cymbalta to Ms. Pokorny, nor did they call on any other neurologist who managed her Cymbalta treatment or tapered her off the medicine. *See* Joint Mot. to Amend Scheduling Order at 2. They called only on Dr. Ziegler or Dr. Jessica Anderson, two primary care physicians who were not involved in counseling Ms. Pokorny on whether to take Cymbalta or how to discontinue it. While Dr. Ziegler authorized refills for Ms. Pokorny's Cymbalta prescription for a limited period at the request of her neurologist, Dr. Anderson had an even more limited role in Ms. Pokorny's care. Ms. Pokorny saw Dr. Anderson only once, approximately a month after she stopped taking Cymbalta completely. *See* Pokorny Dep. at 68:15-19; 192:9-20, Ex. 2. At that appointment, Dr. Anderson simply prescribed Ms. Pokorny Ambien, at her request, to help her sleep. *Id.* at 203:7-11. Thus, Lilly objected to production of their files due to their marginal relevance.

As Plaintiffs' note in their motion, in the course of the parties' discussions regarding discovery, Plaintiff proposed to withdraw their request for these files if Lilly would concede the central medical causation question in the case. Although Lilly has endeavored to work with Plaintiffs toward an agreement on the discovery at issue, Lilly declined to concede a major

[2] Plaintiffs continue to refer to "custodial files" in their motion. Pursuant to the agreed-upon search protocol, Lilly has searched sales representatives' emails and attachments as archived on a centralized server. *See* Joint Motion to Amend Scheduling Order. Lilly understands the parties' continuing dispute to relate solely to the emails and attachments to those emails for the four representatives identified above, not to documents from other potential sources.

element of Plaintiffs' case—that Ms. Pokorny suffered discontinuation symptoms and that they were caused by stopping Cymbalta—in exchange for Plaintiffs' withdrawal of their requests, none of which have any bearing on this issue. Pl. Mem. at 5-6.

LEGAL STANDARD

"[I]t is well established that the district court has wide discretion in establishing the confines of discovery." *Global Sessions LP v. Travelocity.com LP*, No. 6:10cv671 LED–JDL, 2012 WL 1903903, at *2 (E.D. Tex. May 25, 2012). Discovery of non-privileged information is permissible if "'reasonably calculated to lead to the discovery of admissible evidence'" related to the claim or defense of any party. *Marin v. Gilberg*, No. V-07-62, 2009 WL 426061, at *2 (S.D. Tex. Feb. 19, 2009) (quoting Fed. R. Civ. P. 26(b)(1)). The party seeking discovery "bears the burden of showing that the materials and information sought are relevant to the action or will lead to the discovery of admissible evidence," and only when the moving party meets this burden, does the burden shift to the opposing party to show the discovery is not relevant or is outweighed by potential harm. *Abraham v. Alpha Chi Omega*, 271 F.R.D. 556, 559 (N.D. Tex. 2010). Moreover, "practical considerations dictate that the parties should not be permitted to roam in shadow zones of relevancy and to explore matter which does not presently appear germane on the theory that it might conceivably become so." *Munoz v. State Farm Lloyds*, No. B-04-141, 2008 WL 4533932, at *2 (S.D. Tex. Oct. 9, 2008) (internal quotation marks omitted). To the contrary, parties have "'no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings.'" *Kaiser Aluminum & Chem. Corp. v. Willis of Md., Inc.*, No. Civ.A. 02-0944, 2003 WL 21750631 at *1 (E.D. La. July 28, 2003) (quoting Fed. R. Civ. P. 26(b)(1) Advisory Comm. Note (2000)).

"Rule 26(b) commands that all discovery be both relevant and proportional." *In re: Xarelto (Rivaroxaban) Prods. Liab. Litig.*, No. MDL 2592, --- F.R.D. ---, 2016 WL 311762, at

*4 (E.D. La. Jan. 26, 2016). Under this rule, the scope of discovery is limited to nonprivileged, relevant materials that are "proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1); *see also Doe v. Catholic Soc. of Religious and Literary Educ.*, No. H-09-1059, 2009 WL 4506560, at *1 (S.D. Tex. Dec. 3, 2009) (citing Fed. R. Civ. P. 26(b)(2)(C)(iii)). While the concept of proportionality has long formed part of Rule 26, it was recently highlighted by the 2015 amendments to the rule, which "restore[d] the proportionality factors to their original place in defining the scope of discovery" in subsection (b)(1) to "reinforce[] the Rule 26(g) obligation of the parties to consider these factors in making discovery requests . . ."[3] Fed. R. Civ. P. 26(b)(1) Advisory Comm. Note (2015). "[T]he party seeking discovery is required to comply with Rule 26(b)(1)'s proportionality limits on discovery requests," *Mckinney/Pearl Rest. Partners, L.P. v. Metro. Life Ins. Co.*, No. 3:14-CV-2498-B, 2016 WL 98603, at *4 (N.D. Tex. Jan. 8, 2016), and "courts are obligated to limited discovery where 'the burden or expense outweighs its likely benefit,'" *Doe*, 2009 WL 4506560, at *1; *see also In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11–MD–2244–K, 2013 WL 2091715, at *2 (N.D. Tex. May 15, 2013) ("the court may limit discovery of material, even if relevant, where 'the burden or expense of the proposed discovery outweighs its likely benefit'"). The purpose of the 2015 amendments was "to focus discovery . . . on what is truly necessary to

[3] The 2015 "amendments to Rule 26 govern in all proceedings in civil cases thereafter commenced and, insofar as just and practicable, in all proceedings then pending." *Mckinney/Pearl Rest. Partners, L.P. v. Metro. Life Ins. Co.*, No. 3:14-CV-2498-B, 2016 WL 98603, at *3 (N.D. Tex. Jan. 8, 2016).

resolve the case . . .” *Kissing Camels Surgery Ctr., LLC v. Centura Health Corp.*, No. 12-CV-03012-WJM-NYW, 2016 WL 277721, at *1 (D. Colo. Jan. 22, 2016) (citing Roberts, C.J., 2015 Year-End Report on the Federal Judiciary, *available at http://www.supremecourt.gov/publicinfo/year-end/2015year-endreport.pdf*)

ARGUMENT

Plaintiffs’ motion to compel seeks discovery with only tenuous relevance to the claims in this case and far outstrips any reasonable notion of proportionality. Plaintiffs’ claims center on whether Lilly failed to warn Ms. Pokorny’s prescribing physicians about the risk of discontinuation. Accordingly, Plaintiffs have had the opportunity not only to review emails from the files of sales representatives who called on Dr. De Saibro and Dr. Ibrahim but also to depose them. Materials from sales representatives who had no contact with doctors who managed Ms. Pokorny’s Cymbalta treatment or tapered her off Cymbalta bear no conceivable connection to that claim. The requested discovery would come with the attendant burdens of any production in modern litigation—the costs of upload, attorney review for responsiveness and privilege, and production—and the burden of such additional discovery on top of the immense discovery already provided in this matter bears no reasonable proportion to the needs of this case.

I. The Discovery Sought by Plaintiffs Has Minimal Relevance

Plaintiffs’ central premise is that “Lilly’s communications with all of Plaintiff Patti Pokorny’s treating doctors—not just the prescribing doctor or the doctor who oversaw her tapering regimen—are relevant.” Pl. Mem. at 7. In support of this assertion, however, Plaintiffs point to examples highlighting the relevance of *prescribing* physicians. Plaintiffs cite the directed verdict in the Cymbalta discontinuation trial in *Hexum v. Eli Lilly & Co.*, No. 2:13-cv-02701-SVW-MAN (C.D. Cal. Aug. 18, 2015), which hinged on evidence concerning the prescribing physician’s knowledge. Pl. Mem. at 7. Other cases cited by Plaintiff also focused on

discovery related to communications to prescribing physicians. *See In re Actos (Pioglitazone-Prods. Liab. Litig.)*, No. 6:11-MD-2299, 2013 WL 4776346, at *4-6 (W.D. La. Sept. 3, 2013) (granting discovery of sales representative files to establish whether information known to the defendant was communicated to plaintiff's prescribing physicians); *Levaquin Prods. Liab. Litig.*, No. MDL 08-1943 JRT, 2009 WL 10424741, at *3 (D. Minn. Nov. 25, 2009) (ordering production of "documents in the possession of sales representatives who called on bellwether plaintiffs' prescribing doctors"); *Cunningham v. Smithkline Beecham*, 255 F.R.D. 474, 479 (N.D. Ind. 2009) (considering discovery of files of sales representatives who called the plaintiff's prescribing physician). Plaintiffs fail to cite a single case specifically supporting their argument that physicians who simply recorded Ms. Pokorny's alleged symptoms have the same relevance as the doctor who made the decision to prescribe Cymbalta to her. The adequacy of the Cymbalta warning to the physician who initially prescribed Cymbalta to Ms. Pokorny and the prescribing decision itself are paramount in this case, and the discovery sought here relating to after-the-fact treating physicians does not help resolve those issues.

Further, Plaintiffs cite no support for their assertion that "courts and juries deciding other Cymbalta withdrawal cases have focused on whether plaintiffs sought treatment for their withdrawal symptoms and whether plaintiffs were diagnosed with Cymbalta withdrawal." Pl. Mem. at 7. To the extent that is true, Plaintiff does not explain how sales representative files shed light on these factual issues, which are more likely to be illuminated by doctors' medical records (which Plaintiffs have) or doctors' testimony (which Plaintiffs have not sought). Moreover, Plaintiffs' prediction that "Lilly's anticipated defenses focus on the treating doctors' knowledge of Cymbalta and its risks," Pl. Mem. at 9, is undermined by the fact that Lilly has not sought to depose Drs. Ziegler or Anderson. Dr. Anderson saw Ms. Pokorny only once and at

least a month after she finished tapering off Cymbalta, and Dr. Ziegler only authorized refills of Cymbalta for Ms. Pokorny for a period that ended months before she began to taper off the medicine. Lilly has no intention of focusing this case on their knowledge, and discovery on their communications with sales representatives will not help resolve the issues in this case.

II. Lilly Has Produced Extensive Information on its Communications With Doctors About Cymbalta

Lilly has produced a robust universe of materials on Cymbalta's marketing and promotion, much of it touching on information Lilly communicate to doctors, including:

- Advertisements and promotional materials: Lilly has produced over 15,000 documents comprising all advertisements and promotional materials directed either at healthcare professionals or consumers, as submitted to the FDA's Office of Prescription Drug Promotion.
- Spreadsheets tracking sales calls to Ms. Pokorny's doctors: Lilly has produced spreadsheets showing every visit made by Lilly sales representatives and third-party contractors (NovaQuest) to Plaintiff's prescribing physicians. These spreadsheets include details about the type of activity conducted at each visit.
- Cymbalta brand plans: Lilly has produced annual brand strategy documents developed by the Cymbalta brand team, which included marketing employees.
- Performance-based metrics from Lilly's incentive compensation system: Lilly has agreed to produce performance-based metrics that are used to determine the bonuses awarded to Lilly sales representatives.

Although Lilly does not concede the ultimate admissibility of these documents at trial, the materials, among others, go directly to the issues of ostensible concern to Plaintiffs—Lilly's communication with doctors, including Ms. Pokorny's doctors. Plaintiffs have also had the

opportunity to depose three sales representatives, including one, Ms. Salas, who called on Ms. Pokorny's tapering physician during the same time period that other sales representatives were calling on Drs. Ziegler and Anderson.

Indeed, it is worth noting that with this vast array of information, three Cymbalta discontinuation trials involving four plaintiffs were tried to verdict without the need for any discovery directly from sales representatives' files. *See Hagan-Brown v. Eli Lilly & Co.*, 1:14-cv-01614-AJT-JFA (E.D. Va. Sept. 1, 2015) (jury verdict for Lilly on warning adequacy); *Ali v. Eli Lilly & Co.*, 1:14-cv-01615 (AJT/JFA) (E.D. Va. Sept. 1, 2015) (jury verdict for Lilly on warning adequacy); *Herrera v. Eli Lilly & Co.*, No. 2:13-cv-02702 (C.D. Cal. Aug. 10, 2015) (defense verdict for Lilly on all claims); *Hexum v. Eli Lilly & Co.*, No. 2:13-cv-02701-SVW-MAN (C.D. Cal. Aug. 18, 2015) (directed verdict for Lilly entered at close of plaintiff's case). Those cases concerned the same claims at issue in the present case. And parties have "'no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings.'" *Kaiser Aluminum & Chemical Corp.*, 2003 WL 21750631 at *1 (quoting Fed. R. Civ. P. 26(b)(1) Advisory Comm. Note (2000)).

In this present case, Lilly has gone far beyond the discovery in prior Cymbalta cases that proceeded to trial by producing responsive files of four sales representatives who called upon Ms. Pokorny's prescriber and the doctor who handled Ms. Pokorny's tapering process. This production should provide Plaintiffs not only with information about the exact communications between Lilly and these key doctors, but also about what documents are generally contained in sales representative files. In particular, previously produced emails from Ms. Salas, which cover a similar period as the discovery at issue here, already provide Plaintiffs with information about the type of interactions Lilly sales representatives had with doctors regarding Cymbalta at that

time. Additional discovery from sales representatives who called on doctors with only a minimal role in Ms. Pokorny's treatment with Cymbalta would add little to the body of discovery bearing on the issues in this case.

III. Plaintiffs' Discovery Proposal Violates Principles of Proportionality

Even if the Court finds that the documents compelled here are relevant—and Lilly maintains that they are not—in order for these materials to fall within the scope of discovery, the Court must also find that they are "proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." *Mckinney*, 2016 WL 98603, at *3 (quoting Fed. R. Civ. P. 26(b)(1)). "[W]hen discovery requests approach the outer bounds of relevance and the information sought may only marginally enhance the objectives of providing information to the parties or narrowing the issues, the court must then weigh the request with the hardship to the party from whom the discovery is sought." *Piazza's Seafood World, L.L.C. v. Odom*, No. 07–413–BAJ–CN, 2011 WL 3664437, at *2 (M.D. La. Aug. 19, 2011).

Here, Plaintiffs allege injuries resulting from Cymbalta discontinuation that, according to Ms. Pokorny's medical records, lasted no more than two months and produced no lasting physical symptoms. *See supra* at page 4. Plaintiffs do not claim any lost wages or medical expenses. *See* Pokorny Dep. at 227:25-228:12, Ex. 2. As discussed above, the requested files do little to resolve the core issues in this case. Furthermore, producing the discovery sought places a burden on Lilly not justified by its marginal relevance. Plaintiffs contend that Lilly's prior production of 517 documents demonstrates that producing this discovery would not be unduly burdensome. However, this volume does not fully represent the efforts behind the production.

Collecting these files requires running searches across both Lilly's current and archived email systems for a particular sales representative's name in the to/from/cc/bcc fields and then applying the agreed-upon search terms across those isolated collections. The results must then be de-duplicated and reviewed for privilege and relevance. Plaintiffs' argument that Lilly could alleviate this burden by foregoing a relevance review asks Lilly to abandon the contours of discovery under Rule 26. Lilly should not be penalized for insisting on procedures that limit its production to only relevant documents in the scope of discovery, and a relevance review is useful and appropriate to determine that the produced documents are in fact relevant. *See Makowski vs. SmithAmundsen LLC*, No. 08 C 6912, 2012 WL 1634832, at *3 (N.D. Ill. May 9, 2012) ("The Court will not waste time assessing . . . the applicability of a claim of privilege as to irrelevant documents that happen to contain a search term but have nothing to do with the issues in this lawsuit. . . . Even non-privileged materials may be withheld if they are not responsive to one of Plaintiff's document requests."); *see also* The Sedona Conference Commentary on Achieving Quality 25 (Dec. 2013), Ex. 7 ("Although all of these review tools are quite useful in reducing the time spent in reviewing ESI, in most present-day litigation there will still, to a greater or lesser extent, be a need to review manually some portion of the document population to determine responsiveness to a particular e-discovery request.").

While Lilly recognizes this is not an overwhelming burden, it nevertheless outweighs the likely benefit of such peripheral discovery. Given the transient nature of Plaintiff's alleged injuries, the limited alleged economic damages, and the marginal importance of the proposed discovery, the proportionality principles of Rule 26 dictate that such discovery is unjustified.

CONCLUSION

For the foregoing reasons, Lilly respectfully asks the Court to deny Plaintiffs' motion to compel production of the four sales representatives' files in its entirety.

Respectfully Submitted,

Dated: February 12, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of February, 2016, I served Plaintiffs' counsel in this action with a copy of Defendant's Opposition to Plaintiffs' Motion to Compel the Production of Sales Representatives' Custodial Files by electronic mail to the following addresses:

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